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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,598	04/27/2007	John E. O'Gara	59894US(49991)	3666
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EDWARDS ANGELI, PALMER & DODGE LLP			EXAMINER	
P.O. BOX 55874			LOEWE, ROBERT S	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1766	
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			01/25/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/587,598	O'GARA, JOHN E.
	<b>Examiner</b> ROBERT LOEWE	Art Unit 1766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 December 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-16,19-34,36,52 and 53 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-16,19-34,36,52 and 53 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-946)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_

## DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/10 has been entered.

### Response to Arguments

Applicant's arguments/remarks, filed on 12/29/10, have been fully considered. Applicant's arguments with respect to the instant have been considered but are moot in view of the new ground(s) of rejection.

The obviousness double patenting rejection made in the previous Office action is wholly maintained.

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7,8 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motokawa et al. (J. Chromatography A, 2002, 961, 52-63).

Claims 1-4: Motokawa et al. teaches monolithic silica columns which are prepared from tetramethoxysilane (TMOS) and methyltrimethoxysilane (MTES) (abstract and section 3). Motokawa et al. further teaches that surface modification of the monolithic silica was undertaken

by continuously feeding a solution of octadecyldimethyl-N,N-diethylaminosilane (experimental section). It is submitted that both prior to, and after surface modification, the silica monoliths prepared by Motokawa et al. satisfies the limitations of instant claim 1. Specifically, employment of a mixture of TMOS and MTES ensures the formation of an inorganic/organic hybrid monolith (owing to the presence of the methyl groups from the MTES). Figure 2 of Motokawa et al. clearly shows that the hybrid silica monoliths are porous. Given that mixtures of TMOS and MTES are employed, the interior of the silica monoliths are comprised of  $\text{SiO}_2$  (Q units) and  $\text{CH}_3\text{SiO}_{3/2}$  units (T units). Such a situation satisfies formula (II) of instant claim 1. The surface of the hybrid silica monolith inherently possesses surface hydroxyls owing to the incomplete condensation of the hydrolyzed TMOS and MTES. That is to say, the surface of the hybrid silica monolith, prior to surface modification with octadecyldimethyl-N,N-diethylaminosilane has surface units which include, but is not limited to,  $(\text{HO})\text{SiO}_{3/2}$ . These surface groups are bound to the same units found in the interior of the monolith ( $\text{SiO}_2$  and  $\text{CH}_3\text{SiO}_{3/2}$ ). In this case, the surface of the porous hybrid inorganic/organic silica monolith has units which satisfies formula (IV) of instant claim 1 with  $\text{R}^4$  being hydroxyl. Instant claim 1 further claims that the hybrid silica monolith possesses from 1-99% of B units and 1-99% of A units. It is submitted that such a range effectively captures all possible structures when preparing a hybrid silica monolith using TMOS and MTES. It is clear that Motokawa et al. is suggestive of employing at least an equimolar amount of TMOS and MTES and not situations where less than 1% of either TMOS and MTES are employed. Given this, a person having ordinary skill in the art would have found it obvious to prepare porous hybrid silica monoliths in the manner taught by Motokawa et al. employing various amounts of TMOS and MTES to determine how the ratios between the two silane compounds affect the properties of the thus prepared monoliths, including pore size and chromatographic efficacy. It is submitted that amounts which would correlate to structures which satisfy the limitations of instant claims 2 and 3 would also be obvious for the same reasons given above and would be achievable with no undue experimentation and with a reasonable expectation of success.

Claims 7 and 8: Further, after surface modification with octadecyldimethyl-N,N-diethylaminosilane, it is submitted that the hybrid silica monolith would have units which

satisfies formula (V) of instant claim 7, with R<sup>5</sup> being equal to methyl groups and R<sup>6</sup> being equal to an octadecyl group.

Claims 30-33: Motokawa et al. teaches the chromatographic separation of compounds using the porous hybrid inorganic/organic silica monoliths taught therein (Figure 6).

Claim 34: While Motokawa et al. does not explicitly teach that columns produced from the monoliths taught therein have a chromatographically enhancing pore geometry, it is submitted that comparison of the monolithic chromatographic columns of Motokawa et al. with other, particle-based chromatographic columns would show that the monolithic columns have superior separation ability for reasons well-known in the art and also taught by Applicants. In this way, the monolithic columns taught by Motokawa et al. would possess a chromatographically enhancing pore geometry.

Claims 1-16, 19-34, 36, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Gara (US Pat. 6,528,167) in view of Motokawa et al. (J. Chromatography A, 2002, 961, 52-63).

Claims 1 and 52: O'Gara teaches and claims hybrid particles for chromatographic separations, wherein said particles have an interior and exterior surface, wherein the particles have the same claimed composition (claim 1). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Motokawa et al. teaches porous inorganic/organic hybrid silica monoliths for chromatographic separations (abstract). O'Gara and Motokawa et al. are combinable because they are from the same field of endeavor, namely, preparation of hybrid organic/inorganic stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by O'Gara into hybrid porous monoliths as taught by Motokawa et al. and would have been motivated to do so since Motokawa et al. teaches that monolithic silica columns afford much lower separation impedance and higher permeabilities than particle-packed columns. Motokawa et al. also teaches that employment of columns based on small particles requires high-pressure which is difficult to achieve for conventional HPLC instrumentation (Introduction).

Instant claim 52 is a product-by-process claim. For such claims, patentability is based on the product itself, and not on its method of production. Therefore, it is submitted that Motokawa et al. provides motivation to prepare silica monoliths using the compositions as taught by O'Gara. A person having ordinary skill in the art would be cognizant of maintaining/preserving the attractive physical property limitations as taught by O'Gara, namely, the specific pore volumes, average pore diameters, specific surface areas and surface concentration of the R<sup>6</sup> groups. Therefore, a person having ordinary skill in the art would have found it obvious to prepare silica-based monoliths having the claimed physical properties as taught by O'Gara. As such, there would not be expected to be substantial differences in structure of the claimed silica monoliths as compared to the silica monoliths which is suggested by the combination of O'Gara in view of Motokawa et al.

Since many of the remaining dependent claims of O'Gara are identical to those as claimed, a summary showing which claims read on the claims of O'Gara is shown below.

Claims 2-6 of O'Gara are identical or substantially identical to instant claims 2-6, respectively.

Claims 7-9: Claims 16-18 of O'Gara are identical to instant claims 7-9.

Claims 10-16: Claims 9-12 of O'Gara are identical or substantially identical to instant claims 9-15.

Claims 19-22: Claims 19-22 of O'Gara are identical or substantially identical to instant claims 19-22.

Claims 23-33: Claims 25-35 of O'Gara are identical or substantially identical to instant claims 23-29.

Claim 34: O'Gara teaches that the inorganic/organic hybrid particles have chromatographically-enhancing pore geometry (17:18-20).

Claim 36: It is submitted that the combination of O'Gara in view of Motokawa et al. renders obvious Applicants claimed method for preparing the porous hybrid inorganic/organic silica monoliths of instant claim 1. Specifically, given the motivation to prepare silica monoliths as taught by Motokawa et al., a person having ordinary skill in the art would follow the basic procedure as taught by Motokawa et al. Specifically, Motokawa et al. teaches preparing a monolithic material by preparing (1) an aqueous solution of starting silanes (which given the

teachings of both O'Gara and Motokawa et al. includes employing TMOS and MTES starting materials) which further comprises surfactant (PEG) and an acidic catalyst (acetic acid, for example), followed by (2) stirring, and (3) placement into a capillary tube where it further reacts and is aged to produce a monolith material. The resulting monolith is then subjected to water and methanol washes. It should be noted that the column is treated with an aqueous basic solution. Therefore, the first water wash constitutes rinsing the monolith material with an aqueous base. It is clear from the teachings of Motokawa et al. that the water wash may take place at elevated temperature since the final aging step of occurs at 120 degrees C. Washing the monolith with methanol constitutes a solvent exchange. Motokawa et al. further teaches drying the monolith. While Motokawa et al. does not explicitly teach that the material is dried at room temperature followed by drying at an elevated temperature under vacuum, it is submitted that a person having ordinary skill in the art understands that only through elevated temperature and application of vacuum does one stand the highest chance of removing all volatiles from the monolith. Further, drying under both heat and vacuum expedites the time required to dry the monolith, which is a more economical way of preparing the final monolithic column. Last, the surface modifications to the monolith in such a way as to prepare surface-modified monolithic columns having the surface groups as taught by O'Gara could be achieved through feeding the respective chemicals which would cause the desired chemical transformations (Si-CH<sub>3</sub> → Si-F → Si-OH → Si-OR).

Claim 53: O'Gara prepares hybrid particles having surface silicon-alkyl groups (example 1). O'Gara further teaches replacing one or more surface silicon-alkyl groups with halo/fluoro groups and with hydroxyl groups (Scheme on columns 15 and 16 and Example 6). O'Gara further teaches further modification of the surface methyl group converted hybrid inorganic/organic particles with a substituted siloxane group followed by end-capping with a trialkylhalosilane (example 9). O'Gara does not teach that the hybrid particles may be converted to porous monoliths. However, Motokawa et al. teaches porous silica monoliths for chromatographic separations (abstract). O'Gara and Motokawa et al. are combinable because they are from the same field of endeavor, namely, preparation of hybrid inorganic/organic stationary phases for column chromatography. At the time of the invention, a person having ordinary skill in the art would have found it obvious to convert the hybrid particles as taught by

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O'Gara into the claimed porous monoliths and would have been motivated to do so since Motokawa et al. teaches that monolithic silica columns afford much lower separation impedance and higher permeabilities than particle-packed columns. Motokawa et al. also teaches that employment of columns based on small particles requires high-pressure which is difficult to achieve for conventional HPLC instrumentation (Introduction).

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 13-17 and 50-55 of copending Application No. 11/631,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because formula (III) of claim 2 of the '341 Application is the same as formula I of instant claim 1 and reads on instant claims 1-3. The recited dependent claims of the '341 Application read on instant claims 4-15.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,250,214 in view of O'Gara (US Pat. 6,528,167).

Claim 1 of the '214 patent is substantially similar in scope for formulae II and III of instant claims 1 and 52. The key difference between the two claims is that the instant claims further have units of formula (IV), which are derived from the surface replacement of silicon-bonded alkyl groups with the silicon-bonded groups, R<sup>4</sup> as claimed. However, such a treatment step of the monoliths of claim 1 of the '214 patent is believed to be obvious given the teachings of O'Gara. Specifically, O'Gara teaches that replacement of the surface silicon-methyl groups with silanol groups result in hybrid particles with improved pH stability and improved chromatographic separation performance including peak tailing (2:20-24). With this knowledge, a person having ordinary skill in the art would have found it obvious to perform the same surface modifications of the hybrid silica particles as taught by O'Gara to the porous hybrid monolith materials as claimed in the '214 patent; the result being the instantly claimed porous inorganic/organic hybrid monolith material.

#### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT LOEWE whose telephone number is (571)270-3298. The examiner can normally be reached on Monday through Friday from 5:30 AM to 3:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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